4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration Pediatric Medical Devices Workshop; Notice of Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following workshop: FDA Pediatric Medical Devices Workshop. This meeting is intended to focus on challenges in pediatric device development--namely, business planning and funding concerns; and how sponsors can most effectively interact with the FDA. The goal of this meeting is to engage and educate pediatric innovators and device industry sponsors.

This educational meeting will consist of live presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. The interactive meeting will also include a “mock” FDA pre-submission meeting for a “mock” pediatric medical device, to illustrate how such encounters may transpire. In addition, attendees will have an opportunity during lunch to engage with Pediatric Device Consortia Grant Program leaders. The meeting will be recorded for subsequent posting on the FDA Web site.

Date and Time: The meeting will be held on September 24, 2012, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. For participants who cannot attend the live meeting, a recorded Web cast will be made available after the meeting.

Contact: Linda Ulrich, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm.5206, Silver Spring, MD 20993-0002, 301-796-8686, FAX: 301-847-8621, email: megan.mcnamee@icfi.com.

Registration: Interested participants may register for this meeting at the following Web site: https://events-support.com/events/FDA_OOPD_Pediatric_Medical_Devices_Workshop. Please note that registration for the live meeting will be limited based on available seating.

If you need sign language interpretation during this meeting, please contact Linda Ulrich at: Linda.Ulrich@fda.hhs.gov by August 24, 2012.

The FDA Pediatric Medical Devices Workshop is supported by FDA's Office of Orphan Product Development and will include participants from the FDA's Center for Devices and Radiologic Health.

(FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Dated: July 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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